K053642

JAN 26 2006

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the OSTEOSET® DBM Pellets.

Submitted By:	Wright Medical Technology, Inc.
Date:	December 29, 2005
Contact Person:	Theresa Leister Regulatory Affairs Specialist
Proprietary Name:	OSTEOSET® DBM Pellets
Common Name:	Bone Void Filler
Classification Name and Reference:	888.3045 – Resorbable Calcium Salt Bone Void Filler Device (Class II)
Device Product Code and Panel Code:	Orthopedics/87/ MQV

DEVICE INFORMATION

A. INTENDED USE

OSTEOSET® DBM Pellets are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. OSTEOSET® DBM Pellets are intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

B. DEVICE DESCRIPTION

OSTEOSET® DBM Pellets are a bone graft material. OSTEOSET® DBM Pellets combine the effects of DBM and OSTEOSET® Pellets. The DBM used in OSTEOSET® DBM Pellets is tested to confirm the osteoinductivity of each DBM lot.

OSTEOSET® DBM Pellets are provided as preformed 3.0 mm or 4.8 mm pellets. The biodegradable, radiopaque pellets are used to fill bone voids and are resorbed in approximately 30-60 days when used according to labeling. This product is supplied sterile for single patient use.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The indications for use and design features of OSTEOSET® DBM Pellets are identical to those of the predicate device. The fundamental scientific technology of the modified device has not changed relative to the predicate device. The safety and effectiveness of the OSTEOSET® DBM Pellets are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

Osteoinductivity Potential Testing

Each lot of demineralized bone matrix (DBM) incorporated into OSTEOSET® DBM Pellets is assayed using either of the following two test methods:

1) *in vitro* assay using human bone forming cells[1], which was correlated to the athymic rat model[2] and clinical results of the assayed DBM[1].
   OR
2) *in vitro* assay for a native protein (BMP-2) as a surrogate test marker for osteoinductive potential[3]. Results from this immunoassay were correlated to the athymic rat model[3]. Although only one native protein is used as the test marker, it is the combination of various proteins that is responsible for its osteoinductive potential.

Testing each lot of DBM with this cell-based bioassay (1) or immunoassay (2) assures that only DBM with osteoinductive potential is used in the OSTEOSET® DBM Pellets.

The osteoinductivity of this combination of DBM and calcium sulfate (OSTEOSET® Pellets) has not been established; therefore, it is unknown to what extent the formulation components may alter the osteoinductive character of the DBM. Additionally, it is unknown how osteoinductivity of the DBM component, measured via either *in vitro* assay, will correlate with human clinical performance of OSTEOSET® DBM Pellets.

Viral Inactivation Potential

The method for processing the DBM contained in OSTEOSET®DBM Pellets was evaluated for its viral inactivation potential. A panel of model potential human viruses representing various virus types, sizes, shapes, and genomes were evaluated. The viral inactivation testing demonstrated suitable viral inactivation potential of the processing method for a wide spectrum of potential human viruses.

1. Wilkins, R.M. (1999) Clinical Effectiveness of Demineralized Bone Matrix Assayed in Human Cell Culture *Advances in Tissue Banking*. 3:113-124.

   This study correlated the results from the *in vitro* bioassay to results in the athymic rat model and clinical results of the DBM.

2. Lindholm TS, Urist MR. A quantitative analysis of new bone formation by induction in compositive grafts of bone marrow and bone matrix. Clin Orthop 1980 Jul-Aug;(150):288-300.

3. Data on file at Wright Medical Technology, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 2006

Ms. Theresa Leister
Regulatory Affairs Specialist
Wright Medical Technologies, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K053642
Trade/Device Name: OSTEOSET® DBM Pellets
Regulation Number: 21 CFR 888.3045
Regulation Name: filler, bone void, osteoinduction (without human growth factor)
Regulatory Class: Class II
Product Code: MBP and MQV
Dated: December 29, 2005
Received: December 30, 2005

Dear Ms. Leister:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson, M.S.
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053642

Device Name: OSTEOSET® DBM Pellets

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OSTEOSET® DBM Pellets are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. OSTEOSET® DBM Pellets are intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053642